TriMed

K102785

Preparation Date: July 26, 2011

AUG 19 2011

510(K) Summary of Safety and Effectiveness

RADIOCARPAL FUSION SYSTEM

Submitted By:	TriMed, Inc. 27533 Avenue Hopkins Santa Clarita, CA 91355 (800) 633-7221
Registration #:	2031009
Prepared By:	Doug Steinberger, QA/RA Manager
Proprietary Name:	Radiocarpal Fusion System
Classification:	Class II: Plate Fixation, Bone HRS – Section 888.3030 Class II: Screw Fixation, Bone HRS – Section 888.3040
Predicate Devices:	K042355 – Synthes LCP Wrist Fusion System K011335 – Synthes One-Third Tubular DCL Plate

Indications for Use:

The TriMed Radiocarpal Fusion System plates and screws are intended for wrist arthrodesis and fixation of fractures of other small bones.

Device Description:

TriMed Radiocarpal Fusion plates are designed to provide total immobilization of the wrist during wrist arthrodesis and for fixation of fractures of other small bones.

The TriMed Radiocarpal Fusion System comprises of bone plates and screws. All plates and screws are similar to predicate devices. TriMed Radiocarpal Fusion plates come in a variety of lengths, bend angles, and screw mating configurations. All plates are designed to accommodate locking and non-locking screws.

TriMed cortical bone screws for the wrist fusion application are available in diameters of 2.7 mm and 3.2 mm. All screws come in a variety of lengths and plate locking conditions. The Radiocarpal Fusion plates and screws are

made of either ASTM F138/139 implant grade stainless steel or ASTM F136 implant grade Titanium alloy.

Substantial Equivalence: Theoretical calculations and mechanical tests in the form of static bending loads have been performed to verify the safety and functionality of the device. Results demonstrate that the physical properties of the TriMed Radiocarpal Fusion Plating System are substantially equivalent to the predicated devices. The new product does not change the intended use or scientific principles used for safe and effective implantation of the device

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

TriMed Inc.
% Mr. Doug Steinberger
QA/RA Manager
28337 Maitland Lane
Saugus, California 91350

AUG 19 2011

Re: K102785
Trade/Device Name: Radiocarpal Fusion Plate System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: July 26, 2011
Received: July 27, 2011

Dear Mr. Steinberger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K102785

Device Name: Radiocarpal Fusion Plate System

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use _____ (Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102785